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10/716,480	11/20/2003	Yoshiya Gunji	US-102	9006

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AJINOMOTO CORPORATE SERVICES, LLC
INTELLECTUAL PROPERTY DEPARTMENT
1120 CONNECTICUT AVE., N.W.
WASHINGTON, DC 20036

EXAMINER	
ODELL, LINDSAY T	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,480	GUNJI ET AL.	
	Examiner	Art Unit	
	Odell Lindsay	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *8 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01 Oct 2004*. and 4/6/2004
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Claims 1-9 are pending.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7, drawn to a DNA encoding a mutant LysE protein and a bacterial transformant of said DNA, classified in class 435, subclass 252.3.

II. Claims 8-9, drawn to a method for producing L-lysine or L-arginine using a bacterium transformed with a DNA encoding a mutant LysE protein, classified in class 435, subclass 106.

3. The groups are distinct, each from the other, because of the following reasons:

Groups I and II are related as product and process of use. The groups can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA of Group I can be used in a materially different process of using the product such as nucleic acid hybridization, which has distinct method steps from those of Group II. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Groups I and II have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Notice of Possible Rejoinder

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

I n the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so**

may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

5. During a telephone conversation with Shelly Guest Cermak on October 1, 2004, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-9 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Thus, claims 1-7 will be examined herein.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

6. The instant application is granted the benefit of priority for the foreign application 2002-336315 filed in Japan on November 20, 2002 as requested in the declaration.

Receipt is acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d) or (f), which papers have been placed of record in the file. Said papers are not in English and, thus, cannot be

used to pre-date any intervening prior art between the filing date of the instant application and the filing date of the foreign priority documents.

Information Disclosure Statement

7. The information disclosure statement (IDS) filed October 1, 2004 has been reviewed, and its references have been considered as noted by the Examiner's initials on the attached copy.

8. The information disclosure statement filed April 6, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The following references were not considered for the reasons described below:

a) The submitted copy of the referenced document Teizi *et al.* is incomplete.

All other documents in said Information Disclosure Statement were considered as noted by the examiner's initials in the attached copy.

Drawings

9. The drawings have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

Compliance with the Sequence Rules

10. The sequence listing, filed in computer readable form (CRF) and paper copy on April 02, 2004, has been received and entered. However, the instant application fails to fully comply with

the sequence rules. The statement regarding the sameness of the CRF and the paper copy of the sequence listing, filed on April 02, 2004, is not in compliance with the sequence rules because the statement is not signed. A statement over signature is required.

Objections to the Specification

11. The use of the trademarks "EASY TRAP" and "PYROBEST" have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. Please see pages 23, 24, 32, 33 and 36 of the specification for instances of improper trademark use.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Objections to the Claims

12. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Item B of claim 3, drawn to a DNA hybridizable to SEQ ID NO: 1 or a probe prepared from said nucleotide sequence, does not further limit claim 2, drawn to a DNA encoding a mutant LysE protein whereby at least the glycine residue at position 56 is mutated to another residue. A probe of item B is a single-stranded DNA or RNA molecule of defined sequence that can base-pair to a second DNA or RNA molecule that contains a

complementary sequence, and is used to detect a given nucleotide sequence (Current Protocols in Molecular Biology, Chapter 5. p. 2.10.1. 1993). Because a probe is single-stranded, it could consist of either a sequence that hybridizes to the anti-sense or sense strand of SEQ ID NO: 1. A single stranded probe that hybridizes to a sequence within the sense strand of SEQ ID NO: 1 is anti-sense, and does not encode a LysE protein or a mutant LysE protein. The probe, therefore, does not further limit claim 2. In addition, a sense probe that hybridizes to the anti-sense strand is expected to hybridize to a sequence within SEQ ID NO: 1, and not the entirety of SEQ ID NO: 1. A sense probe would, therefore, encode a fragment of the LysE protein, which does not further limit claim 2, but broadens it. If the probe were to hybridize to the entire anti-sense strand of SEQ ID NO: 1, it would encode the wild-type LysE protein instead of a mutant LysE protein, which would also broaden the scope of the claim, instead of limiting it. Correction is required.

Claim Rejections 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicant regards as the invention. The term "**homologous** protein thereof" (emphasis added) is unclear as to the metes and bounds it imparts on the claimed subject matter. Although examples of a "homologous" LysE gene are outlined in the specification, a definition for the term "homologous" is not given for a LysE gene or a LysE protein. In addition, the term

"homologous" is not clearly defined in the art with a single meaning. It is not clear whether the term "homologous", as used in the claims, refers to structural or functional homologs, nor is it clear what level of similarity must exist for a protein to be considered a homolog. Clarification is required.

14. Claims 1-4 and 6-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicant regards as the invention. The term "L-lysine **analogue**" (emphasis added) is unclear as to the metes and bounds it imparts on the claimed subject matter. A definition for the term "L-lysine **analogue**" (emphasis added) is not disclosed in the specification. In addition, the term "L-lysine analogue" is not clearly defined in the art with a single meaning. It is not clear whether the term "analogue", as used in the claims, refers to a structural or functional analogue, nor is it clear what level of similarity must exist for a compound to be considered an analogue. Clarification is required.

15. Claims 1-5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicant regards as the invention. The term "methanol-assimilating bacterium" is unclear as to the metes and bounds it imparts on the claimed subject matter as based on the specification. In paragraph [029], the disclosure teaches that:

> "In the present invention, the methanol-assimilating bacterium, that is, methylotroph, means a bacterium which can grow by utilizing methanol as a major carbon source, and in which the function of the LysE protein is expressed when the DNA of the present invention is introduced."

The term "major" in the phrase "major carbon source" is a relative term that renders the claim indefinite. The term "major" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Is a "major carbon source" one that supplies, for example, 30%, 50%, 75%, or 90% of total carbon? A carbon source that supplies 25% of total carbon could be considered major if all other sources that supply the remaining 75% of carbon each supply less than 25%. Clarification is required.

In addition, where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "methanol-assimilating bacterium" in claims 1-5 is defined by the specification as a "methylotroph," meaning "a bacterium that can grow by utilizing methanol **and in which the function of the LysE protein is expressed when the DNA of the present invention is introduced**," (emphasis added). However, the accepted meaning of a methylotroph, is "an organism that can grow on organic compounds containing no carbon-carbon bonds (Pest Management Glossary, www.pestmanagement.co.uk/lib/glossary)." Does "methanol-assimilating bacterium" as used in the claims encompass a methylotroph bacterium that necessarily expresses the LysE protein of their invention? The term is indefinite because the specification redefines the term with a definition that is inconsistent with the art.

16. Claims 2-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicant regards as the invention. The phrase "at least the glycine residue at position 56" is unclear as to the metes and bounds of the claimed subject matter. The terminology "at least" implies that the protein may be mutated in some other way in addition to the replacement of the 56th glycine residue. An additional mutation, such as a deletion or insertion could result in a change in the position of said glycine residue. It is unclear how to identify said 56th glycine residue, in this case. Clarification is required.

17. Claim 3 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicant regards as the invention. The "stringent conditions" included in item B of the claim are not defined in the specification, nor are they clearly defined in the art. While the specification provides examples of "stringent conditions" (paragraph 0046), the metes and bounds they impart on the claimed subject matter are not clear. For example, one skilled in the art cannot surmise exactly which salt concentration to use in the hybridization conditions. Clarification is required.

18. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicant regards as the invention. Item B of claim 3 is drawn to a probe prepared from SEQ ID NO: 1, which encodes a wild-type LysE protein. The claim, however, is dependent on a claim drawn to a DNA encoding a mutant LysE protein whereby at least the glycine residue at position 56 is replaced with another

amino acid residue (claim 3). Therefore, claim 3 is confusing because it is not clear whether the probe is meant to encode a mutant sequence, a wild-type sequence, or if the probe is meant to be a distinguishing probe. In addition, a probe prepared from SEQ ID NO: 1 does not necessarily encode a LysE protein of any kind. It is well known in the art that a probe is a tool for analyzing DNA. A probe is a single-stranded DNA or RNA molecule of defined sequence, that can base-pair to a second DNA or RNA molecule that contains a complementary sequence, and is used to detect a given nucleotide sequence (Current Protocols in Molecular Biology, Chapter 2. p. 2.10. 1993). Being single-stranded, the probe could be anti-sense, and hybridize to a sequence within the sense strand of SEQ ID NO: 1. This would mean that the probe would not encode, by itself, any part of a LysE protein. The specification, while it describes the probe (see paragraphs 0046-0047), does not limit the probe to one that hybridizes only to the anti-sense strand of SEQ ID NO: 1, that is to say, a "sense" probe that would encode the LysE protein. In addition, a probe that hybridizes to the anti-sense strand, and is, itself, sense, is expected to hybridize to a sequence within SEQ ID NO: 1, and not the entirety of SEQ ID NO: 1. A sense probe would, therefore, encode a fragment of a mutant LysE protein, and not a mutant LysE protein, on which the claim is depends. Therefore, item B of claim 3 is confusing because it is dependent on a claim drawn to a DNA that encodes a mutant LysE protein; however, it is drawn to a probe prepared from SEQ ID NO: 1, which, as explained above, is a DNA that encodes a fragment of either an unknown protein (if the probe hybridizes to the sense strand of SEQ ID NO: 1) or fragment of the wild-type LysE protein (if the probe hybridizes to the anti-sense strand of SEQ ID NO:1). Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 1-7 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1, upon which claims 2-7 depend, is drawn to a DNA encoding a mutant LysE protein of a coryneform bacterium, or homologous protein, thereof. While the function of said DNA is disclosed in the specification, sufficient structure is lacking.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, DNA encoding a mutant LysE protein derived from a coryneform bacterium is described on pages 5-9. The structure of the genus of the instant DNA is not sufficiently described. Although the specification sufficiently describes the structure of a species in the genus (namely, a DNA encoding a mutant LysE protein which has the amino acid sequence of SEQ ID NO:2, wherein the glycine residue at position 56 is replaced with another amino acid residue), the structure of a representative number of species of the genus, as well as the common characteristics that define the structure of the genus, are not adequately described. The structural limitations in claims 2-3 are unclear. The claim language indicates that additional mutations beyond the mutation at position 56 of mutant LysE protein may be present by stating "**at least** the 56th glycine residue" (emphasis added); however the detailed structure of these additional mutations is not disclosed. One of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure. Therefore, claims drawn to the genus of said DNA are also not adequately described.

20. Claims 1-7 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for a DNA of SEQ ID NO:1, in which a mutation results in glycine residue 56 being replaced by serine, does not reasonably provide enablement for the genus of any DNA that encodes a mutant LysE protein of a coryneform bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The instant claims are drawn to DNA that encodes a mutant LysE protein, which imparts resistance to an L-lysine analogue when introduced into a methanol-assimilating bacterium, and to a

bacterium into which said DNA has been introduced. The ability to make all DNAs that encode mutant LysE protein included in the scope of these claims would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The instant specification teaches SEQ ID NO: 1, a DNA encoding *C. glutamicum* wild-type LysE protein, in which glycine residue 56 is mutated to a serine (G56S), and the DNA encoding the G56S mutant of SEQ ID NO:2, the *C. glutamicum* wild-type LysE protein. The art fully enables a mutant of SEQ ID NO: 1, whereby glycine 56 is mutated to serine in the encoded LysE protein, and any DNA encoding the G56S mutant of SEQ ID NO:2 based on the

degeneracy of the genetic code; yet, the art includes no examples of *C. glutamicum* mutant LysE protein encoding genes. While the instant specification describes and enables means for identifying other mutant LysE encoding genes using *in vitro* mutation, introduction of the DNA into *Methylophilus methylotrophus*, and selection on S-(2-aminoethyl)cysteine containing media, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the nucleotides and polynucleotides within the scope of the claims. The ability to find a mutant LysE encoding gene, which is structurally related to SEQ ID NO:1 and functionally related to mutant G56S, is not equivalent to the ability to make a mutant LysE encoding gene as required by the statute (i.e., "make and use"). No description in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its mutant LysE-nature is maintained except for amino acid residue glycine 56. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

Claim Rejections 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

21. Claims 1-6 are rejected under 35 U.S.C. § 101 because the claimed inventions are directed to non-statutory subject matter. The claims, as written, do not sufficiently distinguish over the DNA as it naturally exists because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. The claims are drawn to a DNA encoding a mutant LysE protein. Although mutations

in the LysE protein may be created in the laboratory, they may also occur naturally. It is not clear that the mutations referred to in the claims are only those engineered in the laboratory. In addition, claims 1 and 4-5 are drawn to DNA encoding a mutant LysE protein homolog. In the broadest interpretation of the claims, a LysE homolog can be wild-type LysE, which occurs naturally. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206, USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g. by insertion of "isolated" or "purified" as taught by pages 22-32 of the specification. See M.P.E.P. § 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

22. Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Vrljic *et al.* (see IDS filed April 6, 2004) as evidenced by Pompejus *et al.* (USPAP 2003/0049804, paragraph [0168]). The instant claim is drawn to a DNA encoding a homolog of a mutant LysE protein of a coryneform bacterium that imparts resistance to a L-lysine analogue when introduced into a methanol-assimilating bacterium.

Vrljic *et al.* teach a DNA that encodes the *Corynebacterium glutamicum* wild-type lysE protein, which, when introduced into *Corynebacterium glutamicum ΔlysEG,* imparts resistance to lysine when said bacterium is grown in the presence of Lys-Ala di-peptide. Vrljic *et al.*

anticipate claim 1 for three reasons. To begin, wild-type lysE protein can be considered to be a functional and structural homolog of a mutant LysE. Secondly, corynebacteria are methanol-assimilating bacteria; Pompejus *et al.* state that it can be advantageous to culture Corynebacteria in mixtures of different carbon sources, such as methanol (Pompejus *et al.*, USPAP 2003/0049804, paragraph [0168]). Lastly, in the broadest interpretation of the claims, a lysine analogue can be considered to be a functional analogue of lysine. Therefore, the DNA taught by Vrljic *et al.* embodies every aspect of claim 1.

Other Art for Comment

23. The following are cited to complete the record:

a) WO 0100843 (Pompejus *et al.*) teaches *Corynebacterium glutamicum* wild-type lysE, which is 100% identical to SEQ ID NO: 1, but not the mutants of the instant claims.

b) EP 1108790 (Nakagawa *et al.*) teaches *Corynebacterium glutamicum* wild-type lysE, which is 100% identical to SEQ ID NO: 1, but not the mutants of the instant claims.

Conclusion

24. Claims 1-7 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsay Odell whose telephone number is 571-272-3445. The examiner can normally be reached on M-F, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kathleen Kerr
Primary Examiner

Lindsay Odell
Examiner
Art Unit 1652

November 12, 2004